REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 42-60 are pending in the present application. Claims 42-58 are directed to a method for treating a person having a vascular disorder, wherein said person has or is at risk of developing unipolar depression. Support for amended claims 42-58 may be found in the present specification at page 6, lines 9-14. Claims 59-60 are directed to a method for treating a person having or at risk of developing unipolar depression. Support for amended claims 59-60 may also be found in the present specification at page 6, lines 9-14.

In the outstanding Official Action, claims 42-60 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that while the specification was enabling for a method for treating unipolar depression and depression-related disorders, the disclosure was not enabling for preventing unipolar depressions and the claimed symptoms thereof. However, as noted above, the claims have been amended to recite methods for treating persons having or at risk of developing unipolar

depression. As a result, applicants believe the present amendment obviates this rejection.

While the Official Action alleges that the specification does not identify the patients that may be at risk of developing such disorders, applicants note that claims 42-58 recite a method for treating a person having a vascular disorder, wherein said person has or is at risk of developing unipolar depression.

Moreover, the Examiner's attention is respectfully directed to the present specification at page 3, line 17 to page 5, line 18, wherein persons were prone to developing depression are identified. Thus, the present disclosure does identify those who are at risk of developing such disorders.

In addition, applicants also submit that this would be within the ability of one of ordinary skill in the art to identify those persons who are susceptible to depression and depression-related disorders. Indeed, the Office Action does not present any evidence to the contrary.

Thus, in view of the above, applicants believe that the present disclosure is enabling for the claimed invention.

At this time, applicants would also like to remind the Examiner that it is a well-founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so

expressed. As a matter of law, the express teaching of the patent specification cannot be contrary by mere speculation and unsupported assertions on the part of the Patent Office as stated by the Court of Customs and Patent Appeals in the case of *In re Binh-Nguyen and Stanhagn*, 181 USPQ 46 (CCPA 1974):

> Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the conjecture of the Patent Office is contrary to the teachings of the specification. Thus, while the Official Action contends that the disclosure does not teach whether the method is intended for someone already suffering from depression or for the general population in that it would place an undue burden of experimentation on one skilled in the art to find suitable methodologies for administering the claimed composition, applicants note that the Official Action fails to present any evidence to support this assertion. As a result, applicants believe that the Patent Office fails to satisfy its burden in showing that the present disclosure is not enabling for claims 42-60.

In the outstanding Official Action, claims 42-48 and 51-60 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, FUGH-BERMAN, MAGGIONI and GROWDON.

Applicants believe that the proposed combination of publications fails to disclose or suggest the claimed invention. HORROBIN is directed to the treatment of depression and anxiety using docosahexaenoic acid or natural antioxidants. However, HORROBIN fails to teach the claimed combination of ingredients, the claimed amounts and the claimed ratios in which the phospholipids are present in the composition.

In an effort to remedy the deficiencies of HORROBIN, the Official Action cites to FUGH-BERMAN, MAGGIONI and GROWDON. As previously noted, MAGGIONI is directed to the effects of phosphatidylserine therapy in geriatric persons with depressive disorders. While the publication explores the possible effects of administering phosphatidylserine on cognitive, affective in behavioral systems in elderly women, MAGGIONI does not disclose or suggest the claimed combination, claimed amounts or claimed ratios.

FUGH-BERMAN is directed to dietary supplements and natural products that might be used to treat psychotherapeutic disorders. FUGH-BERMAN acknowledges that the use of vitamins and amino acids are sole agents for psychiatric symptoms are not strong. Rather, the article discusses that there is no preliminary evidence for the use of folate, tryptophan and phenylalanine to possibly aid the effectiveness of conventional anti-depressants. However, the publication carefully notes that more research should be conducted before concluding whether these

products could be used for the prevention and treatment of various psychiatric disorders.

GROWDON is directed to a process and composition for treating disorders by administering lecithin.

Upon reviewing the publications, applicants believe that none of the publications provide the necessary motivation to combine and modify the publications in a manner so as to obtain the claimed invention. As a result, there is simply no motivation to select the claimed combination, claimed amount and claimed ratios as set forth in the claimed invention.

Indeed, while the Patent Office contends that it would be obvious to optimize the claimed amounts and ratios, the Official Action does not present any evidence that these parameters would be considered as result-effective to one skilled in the art.

At this time, the Examiner is again respectfully reminded that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which uses a recognized result, before the determination of the optimum or workable ranges of the variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

As none of the cited publications teach or characterize the claimed amounts and/or ratios as capable of being optimized, applicants believe that one of ordinary skill in the art would

have lacked the motivation to combine each of the claimed components in their recited amounts and ratios.

The applicants also respectfully request the reconsideration of the declaration submitted in the amendment of December 10, 2004. It is believed that the declaration presents data showing that the combination of the invention is unexpectedly effective for the treatment of depression and its related disorders (see Annexes I and II). The data show that the claimed combination of fatty acids, phospholipids and methionine metabolism factors (Supplement I of Annex II) is better than a diet of fatty acids (control diet of Annex II), a diet of vitamins and fatty acids (control diet of Annex I), and a diet of vitamins and fatty acids supplemented with w-3 fatty acids DHA and EPA (Supplement II of Annex I). Applicants note that none of the cited publications disclose or suggest the unexpected results exhibited by the claimed invention.

Applicants believe that a method for treating unipolar depression comprising the administration of fatty acids, phospholipids and a methionine metabolism factor, let alone in the present ratios or in co-administration with citrate and/or vitamin D3, is not disclosed nor suggest by any of the publications, alone or in combination with each other.

Finally, the Examiner is respectfully reminded that a critical step in analyzing obviousness pursuant to 35 U.S.C. §103(a) is casting the mind back to the time of the invention, to

consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Close adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome, wherein that which only the invention taught is used against its teacher." Indeed, to establish a prima facie case of obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab,* 217 F.3d 1365, 1369-70, 55 USPQ 2d 1313, 1362 (Fed. Circ. 2000). The fact that the prior art could be so modified would not have made the modification itself obvious unless the cited publications themselves suggested the desirability of the modification. *In re Gordon,* 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Circ. 1984).

Thus, in view of the above, applicants believe that the proposed combination fails to render obvious the claimed invention.

In the outstanding Official Action, claim 49 was rejected as allegedly being unpatentable over HORROBIN, GROWDON and POLLACK.

As noted above, applicants believe that HORROBIN and GROWDON fail to disclose or suggest the claimed invention. Applicants believe that Pollack fails to remedy the deficiencies of HORROBIN with GROWDON et al. Indeed, POLLACK et al. is

directed to a composition for treating physiological disorders pertaining to the regulation of the neurotransmitter serotonin. However, POLLACK et al. does not disclose nor suggest a method for treating depression by administering to a patient in need thereof a composition containing the claimed components, amounts and ratios.

Thus, applicants believe that POLLACK et al. fail to remedy the deficiencies of HORROBIN and GROWDON et al.

Claim 50 was rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, GROWDON et al. and TAKEDA. This rejection is respectfully treaversed.

TAKEDA teaches a depressive symptom improvement agent. The agent contains carnitine and vitamin B1. However, the TAKEDA publication does not teach the claimed components, amounts or ratios. As a result, it is believed that the TAKEDA publication fails to remedy the deficiencies of HORROBIN and GROWDON et al.

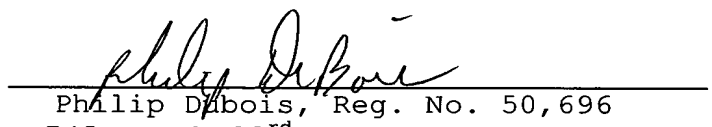
Thus, in view of the above, applicants request that the rejection be withdrawn.

In view of the foregoing remarks and the present amendment, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action, with claims 42-60, as presented. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Philip Dubois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/lk